NDA 20-902

Merck Research Laboratories
Attention: George Latyszonek
Director, Regulatory Affairs
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Mr. Latyszonek:

Please refer to your new drug application (NDA) dated September 30, 1997, received September 30, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for nonprescription Pepcid AC® (famotidine) Coated (gelatin coated, capsule shaped) Tablets, 10 mg.

We acknowledge receipt of your submissions dated July 2, 16, and 29, 1999. Your submission of July 2, 1999 constituted a complete response to our June 21, 1999 action letter.

This new drug application provides for a gelatin coated, capsule shaped, tablet dosage form of nonprescription Pepcid AC® (famotidine) for the treatment or prevention of meal-induced heartburn associated with acid indigestion and sour stomach.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling with the following revisions agreed upon in your submission dated July 29, 1999. Accordingly, the application is approved effective on the date of this letter. The agreed upon revisions are:

1. In the ***Directions*** section of the 6-count blister carton label, the bullet statement "do not use more than 2 gelcaps in 24 hours" will be moved so that it is directly under the previous two bullets.

2. To increase consumers' readability, a space will be added on either side of the hyphens in the storage statement "store at 25º - 30ºC (77º - 86ºF)."

3. The statement "adults and children 12 years and over" will be included under the "**How to use Pepcid AC Gelcaps**" section of the package insert.

4. The flag "New Easy Open Bottle" will be removed after six months of marketing

The final printed labeling (FPL) must be identical to the labeling (package insert, immediate container labels, and carton labels) submitted on July 2, 1999, and include the agreed upon revisions indicated above. These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-902." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this application at this time.

In addition, please submit four copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Gastrointestinal and Coagulation Drug Products, one to the Division of Over-the-Counter Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Albert Rothschild, Project Manager, at (301) 827-2222.

Sincerely,

Charles Ganley, M.D.
Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research